

## REMARKS/ARGUMENTS

### STATUS OF CLAIMS

Applicants have cancelled Claim 5, and the rejections of Claim 5 under 35 U.S.C. §§ 112 and 102 are thus moot. Applicants have also cancelled Claims 86-96, and the restriction requirement is thus moot. Applicants have amended Claim 1. Applicants have added new Claims 97-100. Claims 1-4, 6, 8, 9, 15, and 97-100 are currently pending.

### CLAIM REJECTIONS – 35 U.S.C. § 112

Claims 1-4, 6, 8, 9, and 15 stand rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended Claim 1 to recite “adapted to be positioned” as suggested by the Examiner on page 3 of the Office Action. Claims 2-4, 6, 8, 9, and 15 depend from Claim 1. Thus, Applicants respectfully request removal of the rejection of Claims 1-4, 6, 8, 9, and 15 under 35 U.S.C. § 112, second paragraph.

### CLAIM REJECTIONS – 35 U.S.C. § 102

Claims 1-4, 6, 8, 9 and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,278,432 issued to Ignatius et al. (referred to herein and in the accompanying Declaration of Ronald W. Ignatius as “QDI’s Prior Patent”).

Claim 1 specifies “a plurality of optoelectronic devices positioned within the housing, the optoelectronic devices emitting radiation having an energy density of at least approximately 4 Joules per centimeter squared.”

For anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. *MPEP* § 706.02. QDI’s Prior Patent discloses an array 10 of LEDs 14 that “yield a monochromatic light emission output in 620-680 and/or 700-760 nanometer ranges.” *Ignatius et al.*, col. 3, lines 38-40; col. 4, lines 11-13. The LED array disclosed in QDI’s Prior Patent may have applications such as the irradiation of animal or human tissue. *Id.* at col. 2,

lines 60-64; col. 4, lines 54-56. However, QDI's Prior Patent does not explicitly or impliedly disclose optoelectronic devices that emit radiation having an energy density of approximately 4 Joules per centimeter squared for treating mucositis or any other medical conditions.

The accompanying Declarations of Ronald W. Ignatius and Todd S. Martin provide additional evidence that QDI's Prior Patent is devoid of any disclosure regarding a biostimulation device specifically designed to treat mucositis. Before Applicants designed the device claimed in the Present Application, Mr. Ignatius and Mr. Martin were unaware of any device capable of providing radiation at an energy density of at least approximately 4 Joules per centimeter squared in a relatively short period of time. Mr. Ignatius and Mr. Martin were unaware of any device that could produce a uniform emission of monochromatic light for the treatment of mucositis with the production of a minimal amount of heat. As a result of Mr. Ignatius and Mr. Martin being unaware of a device suitable for treating mucositis, QDI's Prior Patent (i.e., their own prior patent) cannot possibly provide the disclosure necessary for one of ordinary skill in the art to make and use the device claimed in the Present Application without undue experimentation.

Moreover, a functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *MPEP* § 2173.05(g). A functional limitation is often used in association with an element to define a particular capability or purpose that is served by the recited element. *Id.* In Claim 1 of the Present Application, the functional limitation of "emitting radiation having an energy density of at least approximately 4 Joules per centimeter squared" must be evaluated and considered just like any other limitation of the claim. This limitation is used in association with the optoelectronic device element of Claim 1 to define the particular capability and purpose that is served by the optoelectronic device element. As noted above and in the Declarations of Ronald W. Ignatius and Todd S. Martin, this particular capability and purpose for treating mucositis is not disclosed in QDI's Prior Patent.

In light of the above, QDI's Prior Patent does not disclose, teach, or suggest "a plurality of optoelectronic devices positioned within the housing, the optoelectronic devices emitting radiation having an energy density of at least approximately 4 Joules per centimeter squared," as required by Claim 1. Therefore, independent Claim 1 and dependent Claims 2-4, 6, 8, 9, 15, and 97 are allowable.

#### NEW CLAIMS

New Claim 97 depends from Claim 1 and is therefore allowable for the reasons discussed above with respect to Claim 1. New Claim 97 also specifies "wherein the optoelectronic devices emit radiation for a radiation time period of approximately 70 seconds." QDI's Prior Patent is devoid of any disclosure regarding suitable radiation time periods for the treatment of mucositis, much less a specific radiation time period of approximately 70 seconds. Therefore, dependent Claim 97 specifies additional patentable subject matter.

New independent Claim 98 specifies "a cover plate positioned over the plurality of optoelectronic devices in order to electrically isolate the patient from the plurality of optoelectronic devices; and a controller positioned within the housing and coupled to the plurality of optoelectronic devices, the controller adapted to provide power to the plurality of optoelectronic devices for a radiation time period suitable for the treatment of mucositis." As discussed in the declarations of Ronald W. Ignatius and Todd S. Martin, the device of the Present Application was designed to address safety concerns relating to treating humans that were not concerns with the old device used to irradiate plants. QDI's Prior Patent does not disclose a cover plate to electrically isolate the patient from the optoelectronic devices. QDI's Prior Patent also does not disclose a controller for providing power to the optoelectronic devices for a radiation time period suitable for the treatment of mucositis. Therefore, independent Claim 98 and dependent Claims 99-100 are allowable.

CONCLUSION

In view of the foregoing, Applicants respectfully request entry of the amendment and allowance of pending Claims 1-4, 6, 8, 9, 15, and 97-100.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'C. F. Laska' with a stylized flourish at the end.

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